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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,679 12/30/99 BRIEDEN

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BAKER & BOTTS
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NEW YORK NY 10112

HM12/0614

EXAMINER

RAO, M

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/214,679

Applicant(s)

Bried n et al.

Examiner

Manjunath N. Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 16, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-3 and 15-21 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3 and 15-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-3 and 15-21 are now pending in this application.

Election/Restriction

2. Applicant's election of claims 1-3, 15-21 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement and also due to the fact that applicants have canceled non elected claims 4-14 and 22-23, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Drawings

4. This application has been filed with drawings that have been objected to by the Draftsperson. Please see the attached form PTO948 for details.

Claim Objections

5. Claims 15-19 and 20-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to previous claims in the alternative only and may not depend from another multiple dependent claim. See MPEP § 608.01(n).

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6. Claims 2-3 are objected to because of the following informalities: Claims 2 and 3 recite the names of microorganisms without any underlining or using italics lettering. Appropriate correction is required.

7. Claims 15 and 16 are objected because of the following informalities: Claims 15, 16 depend from non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-3 are drawn to “microorganisms” which read on a product of nature. Amending the claim to recite “a biologically pure culture of” and inclusion of other characteristics to show the hand of man would overcome this rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 15-16 and claims 17-21 which depend from claim 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15-16 recites the phrase "if appropriate" in the last line of the claim. It is not clear to the Examiner as to what applicants mean by this phrase.

11. Claim 16 and claims 17-21 which depend from claim 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites the phrase "isolation of this compound and/or" in the last but third line of the claim. It is not clear to the Examiner as to which specific compound applicants are referring to when they recite "this compound".

12. Claims 15, 16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Structural formula for compounds I, II, VII and VIII depicted in claims 15, 16 and 21 are incomplete as they are lacking a methyl group rendering the claims unclear.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-3 and 15-21 which depend from claim 1 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated microorganisms such as *K.oxytoca* PRS1, *K.Oxytoca* PRS1K17, *R. opacus* ID-622, *A.ramosus* ID620, *Bacillus sp.* ID-621, *K.planticula* ID-624, *K.pneumoniae* ID-625 or *Pseudomonas sp.* (DSM 11355) capable of utilizing (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide (THMP) as its sole source of nitrogen does not reasonably provide enablement for claiming any other strain or species of the above microorganisms or any or all microorganisms (including variants and mutants) with the characteristic property of utilizing THMP as sole nitrogen source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-3 and 15-21 are so broad as to encompass any microorganism(s) capable of utilizing THMP as its sole source of nitrogen or any species of the above mentioned genus of microorganisms that have been deposited. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of microorganisms that are broadly encompassed by the claims.

Since applicants have shown that the above characteristic feature is existent only in the deposited microorganisms which produce a specific amidohydrolase enzyme and since applicants have not shown that this above enzyme is produced by all species and strains of the deposited

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microorganisms or all or any other microorganisms, the claims encompass microorganisms that are capable of utilizing THMP as sole source of nitrogen by other mechanisms existing in nature. Applicants have also not shown that using THMP as sole source of nitrogen is only through the pathway that they have described i.e., through the action of the above amidohydrolase enzyme. In nature, microorganisms are known to be a highly varied group of organisms. For example, while some microorganisms produce ATP using a six carbon sugar such as glucose, some others produce the same ATP using a pentose sugar. Thus it is highly possible that there could be alternate pathways of using THMP as sole nitrogen source by microorganisms and applicants have shown the presence of only one such pathway. Furthermore, it is also well known in the art that the different strains within a single species or different species within a single genus can vary in their physical and biochemical characteristics. For example, not all strains of *E.coli* are known to cause food poisoning due to production of a heat stable toxin. As the above characteristic (i.e., use of THMP as sole nitrogen source) of the microorganism is dependent on the enzymes produced by the microorganisms predictability of existence of alternate pathways for use of THMP as sole nitrogen source requires a knowledge of and guidance of the ways to identify and characterize specific microorganism in which the enzyme proteins' structure relates to its function. However, in this case the disclosure is limited to the few microorganisms which have been deposited in a culture collection.

While microbial isolation and identification techniques are known, it is not routine in the art to screen for multiple strains, as encompassed by the instant claims, and a reasonable

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expectation of success in obtaining the desired activity/utility are limited and the results of such identifications are unpredictable.

The specification does not support the broad scope of the claims which encompass all microorganisms with the above characteristics because the specification does **not** establish: (A) that the mechanism involved (enzymatic pathway) in the use of THMP as sole source of nitrogen is universal in all microorganisms and; (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have **not** provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any microorganism with the characteristic of utilizing THMP as sole source of nitrogen. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, identification of a microorganism having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

15. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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These claims are directed to a genus of microorganisms (including variants and mutants) which are capable of utilizing THMP as sole source of nitrogen.

The specification does not contain any other characteristic feature of the encompassed microorganisms apart from the functional characteristic of the capability of utilizing THMP as sole source of nitrogen. The genus of above microorganisms constitutes an extremely large variable genus with many different capabilities and characteristics. Therefore, many unrelated microorganisms are encompassed within the scope of these claims, including mutants and variants. The specification discloses only few (see claim 2) species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. In response to the above rejection applicants may argue that they have described several characteristics of the microorganisms in their specification. However, such argument would not be persuasive to overcome the above rejection. This is because even though applicants have described few other characteristics of the microorganisms, such characteristics apply to only those that the applicants have identified. Applicants have not shown that all other species of the very same microorganisms would have the very same characteristics. Therefore amending the claim to recite only the specific microorganisms (even excluding the functionally equivalent variants and mutants) that applicants have deposited would overcome this rejection.

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Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.


16. Claim 3 is rejected because the invention appears to employ novel microbial strains. Since the microbial strains are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microbial strains have not been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microbial strains. The specification does not disclose a repeatable process to obtain the microbial strains and it is not apparent if the microbial strains are readily available to the public. Accordingly, it is deemed that a deposit of these microbial strains should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the microorganisms under the terms of the Budapest Treaty (page 4) but there is no indication in the specification as to public availability. As the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

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17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao. Ph.D.
June 12, 2001


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